UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AZURITY PHARMACEUTICALS, INC.,	)	
	)	Civil Action No. 21-12870 (MAS) (DEA)
Plaintiff,	)	
	)	
v.	)	
	)	
	)	**Motion Returnable: August 16, 2021**
BIONPHARMA INC.,	)	
	)	**ORAL ARGUMENT REQUESTED**
Defendant	)	

DEFENDANT BIONPHARMA'S BRIEF IN SUPPORT OF ITS MOTION TO DISMISS PURSUANT TO FED. R. CIV. P. 12(b)(6)

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TABLE OF ABBREVIATIONS

Abbreviation	Meaning
’008 patent	U.S. Patent No. 9,669,008 B1
’023 patent or patent-in-suit	U.S. Patent No. 11,040,023 B2
’442 patent	U.S. Patent No. 9,808,442 B2
’482 patent	U.S. Patent No. 10,786,482 B2
’587 application	U.S. Patent Application No. 17/150,587, the prosecution history of which is attached as Ex. V to the Shrestha Declaration
’587 PH	Prosecution history of the ’587 application, attached as Ex. V to the Shrestha Declaration.
’621 patent	U.S. Patent No. 10,918,621 B2
’745 patent	U.S. Patent No. 10,039,745 B2
’868 patent	U.S. Patent No. 10,772,868 B2
’987 patent	U.S. Patent No. 10,154,987 B2
Amneal	Amneal Pharmaceuticals LLC
ANDA	Abbreviated New Drug Application pursuant to 21 U.S.C. § 355(j)
Azurity	Plaintiff Azurity Pharmaceuticals, Inc., successor-in-interest to Silvergate Pharmaceuticals, Inc.
Azurity’s enalapril liquid patent family	’008, ’442, ’745, ’987, ’482, ’868, ’621, and ’023 patents
Bionpharma	Defendant Bionpharma Inc.
Bionpharma’s ANDA	Bionpharma’s ANDA No. 212408
Bionpharma’s ANDA product	The 1 mg/mL enalapril maleate oral solution described in Bionpharma’s ANDA
Bionpharma’s Motion to Transfer	Defendant Bionpharma’s Motion to Transfer Venue Pursuant to 28 U.S.C. § 1404(a)
The common specification	The common specification of Azurity’s enalapril liquid patent

Abbreviation	Meaning
	family
DOE	Doctrine of equivalence
D. Del. 18-1962	*Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 18-1962 (D. Del.) (the first of the First Wave Suits)
D. Del. 19-1067	*Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 19-1067 (D. Del.) (the second of the First Wave Suits)
D. Del. 20-1256	*Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 20-1256 (D. Del.) (the Second Wave Suit)
Epaned® Kit	Azurity's predecessor product to Epaned® (*see Silvergate Pharm., Inc. v. Bionpharma Inc.*, No. C.A. No. 18-1962-LPS, 2021 WL 1751148, at *4 (D. Del. Apr. 29, 2021))
FDA	United States Food and Drug Administration
First Wave Patents	'008, '442, '745, and '987 patents
First Wave Suits	*Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962 and 19-1067 (D. Del.)
JSD	Joint Stipulation for Dismissal entered in the Second Wave Suit (ECF No. 106), so ordered by the Court with a docket entry on May 21, 2021 (Shrestha Decl. Ex. O)
Mosher Decl.	Decl. of Gerold L. Mosher dated Apr. 23, 2021 (Shrestha Decl. Ex. V, '587 PH at BION-ESOL00038480-88)
NDA	New Drug Application pursuant to 21 U.S.C. § 355(b)(1)
Orange Book	FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*
Paragraph IV certification	Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)
PI	Preliminary injunction
POSA	Person of ordinary skill in the art
PTO or Patent Office	United States Patent and Trademark Office
Second Wave Patents	'868, '482, and '621 patents
Second Wave Suit	*Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A.

Abbreviation	Meaning
	No. 20-1256 (D. Del.)
Shrestha Decl.	The Declaration of Roshan P. Shrestha, Ph.D., submitted concurrently herewith
Silvergate	Silvergate Pharmaceuticals, Inc., predecessor-in-interest to Azurity
Third Wave Suit	The instant action, *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 21-12870 (D.N.J.)

Defendant Bionpharma respectfully submits the instant Brief in Support of Its Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6). As explained below, dismissal of Plaintiff Azurity's Complaint for Patent Infringement (ECF No. 1) is warranted on claim preclusion grounds.

INTRODUCTION

This action represents the third wave in a series of lawsuits filed by Plaintiff Azurity against Bionpharma asserting that Bionpharma's ANDA No. 212408—which seeks FDA approval to market a 1 mg/ml enalapril maleate oral solution as generic to Azurity's Epaned® antihypertensive prescription drug product—infringes Azurity's enalapril oral liquid patent family. The First[1] and Second Wave[2] Suits were filed in Delaware Federal court, where the parties have spent over two and a half years litigating seven patents that are in the same family as the '023 patent that is the subject of the instant Third Wave Suit.[3] Chief Judge Stark from the District of Delaware held a 5-day bench trial in the First Wave Suits on February 1-5, 2021. On April 27, 2021, Judge Stark issued a 72-page opinion finding that Azurity failed to prove infringement of the asserted claims of the First Wave Patents and, on April 29, 2021, entered final judgment in Bionpharma's favor. Judge Stark's decision in the First Wave Suits rendered moot Azurity's Second Wave Suit on collateral estoppel grounds, and the Second Wave Suit was dismissed on May 21, 2021 with prejudice, unless Azurity secures a decision on appeal of the First Wave Suits that eliminates the estoppel.

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[1] *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962 and 19-1067 (D. Del.).

[2] *Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 20-1256 (D. Del.).

[3] Bionpharma has moved concurrently herewith for transfer of this Third Wave Suit to the District of Delaware pursuant to 28 U.S.C. § 1404(a).

In the instant Third Wave Suit, Azurity seeks to assert the same cause of action that was litigated by the parties in connection with the First and Second Wave Suits, and that went to final disposition in Bionpharma's favor, by asserting a continuation patent—the '023 patent—with claims that are patentably indistinct from the claims of the First and Second Wave Patents. As explained further below, under Federal Circuit law, including *SimpleAir Inc. v. Google LLC*, 884 F.3d 1160 (Fed. Cir. 2018), Azurity's claims in the instant Third Wave Suit are precluded and the Complaint should be dismissed.

FACTUAL BACKGROUND

I. THE FIRST WAVE SUITS

Bionpharma filed its ANDA back in 2018, seeking approval from the FDA to market its ANDA product as generic to Azurity's Epaned®. ECF No. 1, Compl. ¶ 14. In response, Azurity instituted the First Wave Suits starting in December of 2018 in Delaware Federal court, asserting that Bionpharma's ANDA and the product described therein infringe Azurity's '008, ' 442, '745, and '987 patents ("First Wave Patents"). *Id*. at ¶¶ 14-15. The claims of Azurity's First Wave Patents are directed to: (1) a group of enalapril liquid formulations that contain citric acid and sodium citrate as a buffer system at specific concentrations, sodium benzoate as a preservative at specific concentrations, and that are stable for 12 months at refrigerated conditions (5±3 °C); and (2) methods of treatment using those liquids. *Silvergate Pharm., Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962 and 19-1067, 2021 WL 1751148, at *8-*9 (D. Del. Apr. 29, 2021); Shrestha Decl. Exs. C-F, First Wave Patents at claims.[4] Bionpharma had designed its ANDA product extensively around Azurity's First Wave Patents, including by entirely omitting a buffer from its

[4] As the First and Second Wave Patents are "matters of public record," this Court may take judicial notice of those documents and consider them in connection with Bionpharma's Motion to Dismiss. *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196-97 (3d Cir. 1993); *Genetic Techs. Ltd. v. Bristol-Myers Squibb Co.*, 72 F. Supp. 3d 521, 526 (D. Del. 2014).

formulation, and by utilizing an alternative to the claimed sodium benzoate preservative. *Silvergate*, 2021 WL 1751148, at *1.

The Delaware court held a five day bench trial on February 1-5, 2021 and, on April 27, 2021, issued its Opinion finding the asserted claims of Azurity's First Wave Patents not infringed by Bionpharma's ANDA product, including because Azurity failed to prove the existence of a buffer in Bionpharma's ANDA product, and because the alternative to the claimed sodium benzoate that Bionpharma used in its ANDA product was disclosed in the common specification of the First Wave Patents, but not claimed, and was therefore dedicated to the public. *Id*. at *1. The Court entered final judgement in Bionpharma's favor shortly thereafter. Shrestha Decl. Ex. H, D. Del. 18-1962 ECF No. 270, Final J.;[5] ECF No. 1, Compl. ¶ 14 n.2.

II. THE SECOND WAVE SUIT

Shortly after Bionpharma filed its ANDA, Azurity began filing continuation patent applications seeking considerably broader and different claim coverage, and eventually secured issuance of the '868, '482, and '621 patents ("Second Wave Patents") in late 2020 and early 2021, which were the subject of Azurity's Second Wave Suit. ECF No. 1, Compl. ¶ 16 n.4; Shrestha Decl. Ex. J, Second Wave Suit ECF No. 49, Second Am. Compl.; *id*. at Exs. K-M, Second Wave Patents at covers. As explained above, on April 27, 2021, the Delaware court issued its opinion in the First Wave Suits finding that, *inter alia*, Azurity failed to prove the

[5] As the complaints in the First and Second Wave Suits (Shrestha Decl. Ex. A, D. Del. 18-1962 ECF No. 1; *id*. at Ex. B, D. Del. 19-1067 ECF No. 1), the Final Judgment entered in the First Wave Suits (*id*. at Shrestha Decl. Ex. H, D. Del. 18-1962 ECF No. 270), the Second Amended Complaint in the Second Wave Suit (*id*. at Ex. J, Second Wave Suit ECF No. 49), and the Joint Stipulation for Dismissal ("JSD") entered in the Second Wave Suit (*id*. at Ex. O, Second Wave Suit ECF No. 106) are "matters of pubic record," this Court may take judicial notice of those documents and consider them in connection with Bionpharma's Motion to Dismiss. *Pension*, 998 F.2d at 1196-97; *see also, Toscano v. Conn. Gen. Life Ins. Co.*, 288 F. App'x 36, at *38 (3d Cir. 2008).

existence of a buffer in Bionpharma's ANDA product. Because all of the claims of the Second Wave Patents require a buffer (Shrestha Decl. Exs. K-M, Second Wave Patents at claims), the Delaware court's finding that Azurity failed to prove the existence of a buffer rendered moot Azurity's Second Wave Suit on collateral estoppel grounds, and the parties stipulated to dismissal of the Second Wave Suit, which was so ordered on May 21, 2021. Shrestha Decl. Ex. O, Second Wave Suit ECF No. 106, JSD; Second Wave Suit, May 21, 2021 docket entry. By the express terms of the dismissal order, all claims of the Second Wave Suits were dismissed with prejudice, except in the event "that the Federal Circuit renders a decision whereby collateral estoppel would not apply to bar [Azurity's] assertion of the Second Wave Patents against Bionpharma." Shrestha Decl. Ex. O, Second Wave Suit ECF No. 106, JSD at 3.

III. THE '023 PATENT AND THE INSTANT (THIRD WAVE) SUIT

On January 15, 2021, over two years after Bionpharma filed its ANDA with the FDA and the institution of the First Wave Suits, Azurity filed with the PTO U.S. Patent Application No. 17/150,587, which claims priority to the First and Second Wave Patents. ECF No. 1-1, Compl. Ex. A, '023 patent at cover. On June 22, 2021, the '587 application issued into the '023 patent, and Azurity instituted this Third Wave Suit that same day. ECF No. 1, Compl. The claims of the '023 patent are very similar to the claims of the First and Second Wave Patents, and are directed to enalapril liquid formulations that may contain, but that do not explicitly require, a buffer component, and that are stable for at least 12 months at refrigerated conditions. ECF No. 1-1, Compl. Ex. A, '023 patent at claims. Claim 1, the sole independent claim, recites as follows:

> 1. A stable oral liquid formulation, consisting essentially of:
>
> (i) about 0.6 to about 1.2 mg/ml enalapril or a pharmaceutically acceptable salt or solvate thereof;

> (ii) a sweetener;
>
> (iii) a preservative, wherein the preservative comprises sodium benzoate, a paraben or a mixture of parabens;
>
> (iv) water; and
>
> (v) optionally a flavoring agent;
>
> wherein the formulation is stable at about 5±3° C. for at least 12 months; and
>
> wherein the stable oral liquid formulation has about 95% w/w or greater of the initial enalapril amount and about 5% w/w or less total impurity or related substances at the end of the given storage period.

Id.

During prosecution, the '587 application claims were rejected by the PTO on April 19, 2021: (1) as being obvious in view of the prior art; and (2) on obviousness-type (non-statutory) double patenting grounds,[6] as the PTO viewed the '587 application claims as mere obvious variations of, and patentably indistinct from, the claims of several of the First and Second Wave Patents, including the '008, '745, '868, '482, and '621 patents. Shrestha Decl. Ex. V, '587 Application Prosecution History ("'587 PH"), Apr. 19, 2021 Office Action at 3-11 (BION-ESOL-00038447-455).[7]

[6] The doctrine of obviousness-type double patenting bars an applicant from filing a patent application with claims directed to subject matter that overlaps with, or that is obvious in view of (and therefore patentably indistinct from), claims in an earlier filed application filed by the applicant. *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366, 1373-74 (Fed. Cir. 2014). One crucial purpose of the doctrine is to "prevent an inventor from securing a second, later expiring patent for the same invention." *Id*. Thus, one way to obviate an obviousness-type double patenting rejection is for the applicant to submit a terminal-disclaimer in connection with the later-filed application that ties the term of any patent to issue from the later-filed application to the term of the patent that issues (or issued) from the earlier-filed application. *In re Hubbell*, 709 F.3d 1140, 1148 (Fed. Cir. 2013).

[7] As the prosecution history of the '023 patent is a "matter[] of pubic record," this Court may take judicial notice of the prosecution history and consider it in connection with Bionpharma's Motion to Dismiss. *Pension*, 998 F.2d at 1196-97; *Genetic Techs.*, 72 F. Supp. 3d at 526.

On April 23, 2021, Azurity submitted a Response to the Office Action and an accompanying declaration from one of the inventors, Gerold L. Mosher. Shrestha Decl. Ex. V, '587 PH, Apr. 23, 2021 Response to Non-Final Office Action Dated April 19, 2021 (BION-ESOL00038469-479) ("April 23, 2021 Response"); *id*. at Apr. 23, 2021 Decl. of Gerold L. Mosher (BION-ESOL00038480-88) ("Mosher Decl."). In the Response, Azurity stated that "[t]he stability of the present formulations is described in the instant specification and drawings, e.g., Tables E1 and E2." Shrestha Decl. Ex. V, '587 PH, Apr. 23, 2021 Resp. at 6 (BION-ESOL-00038474). With respect to the PTO's obviousness rejection, Azurity argued that the prior art did not disclose the claimed stability and that the Mosher Declaration showed that the claimed formulations achieved unexpected stability for at least 12 months at refrigerated conditions. *Id*. at 5-10 (BION-ESOL-00038473-78). With respect to the PTO's obviousness-type double-patenting rejection, Azurity submitted a terminal disclaimer disclaiming the terminal portion of the '023 patent that extends beyond the expiration dates of the '008, '745, '868, '482, and '621 patents. *Id*. at 10 (BION-ESOL-00038478); Shrestha Decl. Ex. V, '587 PH, Apr. 23, 2021 Terminal Disclaimer (BION-ESOL00038491-95). On May 18, 2021, the claims of the '023 patent were allowed by the PTO. *Id*. at May 18, 2021 Notice of Allowance (BION-ESOL-00038531-39).

Since the filing of this Third Wave Suit, Azurity has listed to '023 patent in the FDA's Orange Book as covering Epaned®. Shrestha Decl. Ex. W, Orange Book Entry for Epaned®.[8]

[8] As the FDA's Orange Book is a "matter[] of public record," this Court may take judicial notice of that document and consider it in connection with Bionpharma's Motion to Dismiss. *Pension*, 998 F.2d at 1196-97.

ARGUMENT

I. LEGAL STANDARD

A. Fed. R. Civ. P. 12(b)(6)

In deciding a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), this Court is to "accept all factual allegations in the complaint as true, construe the complaint in the light favorable to the plaintiff, and ultimately determine whether plaintiff may be entitled to relief under any reasonable reading of the complaint." *Mayer v. Belichick*, 605 F.3d 223, 229 (3d Cir. 2010).

B. Claim Preclusion

Claim preclusion is a question of law. *Brain Life, LLC v. Elekta Inc.*, 746 F.3d 1045, 1052 (Fed. Cir. 2014). Claim preclusion bars "the relitigation of a claim, or cause of action, or any possible defense to the cause of action which is ended by a judgment of the court." *Id.* at 1053 (internal quotations omitted). "Under Third Circuit law . . . claim preclusion principles require: '(1) a final judgment on the merits in a prior suit involving[](2) the same parties or their [privies]; and (3) a subsequent suit based on the same cause of action.'" *Senju Pharm. Co., Ltd. v. Apotex Inc.*, 746 F.3d 1344, 1348 (Fed. Cir. 2014) (quoting *CoreStates Bank, N.A. v. Huls Am., Inc.*, 176 F.3d 187, 194 (3d Cir. 1999)). "A dismissal with prejudice operates as an adjudication on the merits, so it ordinarily precludes future claims." *Papera v. Pa. Quarried Bluestone Co.*, 948 F.3d 607, 611 (3d Cir. 2020) (citations and internal quotations omitted). Whether a cause of action in a patent case is the same as, or different from, another cause of action, is analyzed under Federal Circuit law. *Id.* "[C]laim preclusion bars both claims that were brought as well as those that could have been brought." *Brain*, 746 F.3d at 1053; *C.I.R. v. Sunnen*, 333 U.S. 591, 597 (1948).

"The defense of claim preclusion, . . . , may be raised and adjudicated on a motion to dismiss and the court can take notice of all facts necessary for the decision. . . . Specifically, a court may take judicial notice of the record from a previous court proceeding between the parties." *Toscano*, 288 F. App'x at *38; *see also, Senju*, 746 F.3d at 1346 (dismissal based on claim preclusion affirmed on appeal).

II. CLAIM PRECLUSION BARS THE INSTANT THIRD WAVE SUIT

Azurity is asserting the same cause of action in the instant Third Wave Suit that was previously litigated by the parties in connection with the First and Second Wave Suits, and Chief Judge Stark's Final Judgment of non-infringement in the First Wave Suits, and His Honor's dsimissal with prejudice of the Second Wave Suit, therefore preclude Azurity's infringement claims in the instant Third Wave Suit as a matter of law. *SimpleAir*, 884 F.3d at 1165-69.

A. The First and Second Wave Suits Were Adjudicated on the Merits

As explained above, the First Wave Suits—which involved Azurity's claims that Bionpharma's ANDA and ANDA product infringe Azurity's First Wave Patents—ended with a final judgment of non-infringement in Bionpharma's favor. The Second Wave Suit—which involved Azurity's claims that Bionpharma's ANDA and ANDA product infringe Azurity's Second Wave Patents—ended in a dismissal with prejudice,[9] which operates as an adjudication on the merits. *Papera*, 948 F.3d at 611.

[9] It matters not that the dismissal with prejudice includes a carve out in the unlikely event that the Federal Circuit renders a decision in connection with the appeal of the First Wave Suits that eliminates collateral estoppel of the Second Wave Suit. Barring such an unlikely outcome, the "dismissal with prejudice operates as an adjudication on the merits" and "ordinarily precludes future claims." *Papera*, 948 F.3d at 611.

B. The Same Parties Are Involved

Azurity is the successor-in-interest to Silvergate, the plaintiff in the First and Second Wave Suits. ECF No. 1, Compl. ¶ 3. There can be no dispute that the same parties who were involved in the First and Second Wave Suits are involved in the instant Third Wave Suit.

C. The Same Cause of Action Is Involved

In the patent context, "[c]laim preclusion will generally apply when a patentee seeks to assert the same patent against the same party and the same subject matter." *Senju*, 746 F.3d at 1349. However, recent Federal Circuit case law has made clear that an adjudication on the merits with respect to a first patent in a previous suit will bar a subsequent suit alleging infringement of a second, different patent (such as a continuation patent) if assertion of the different patent represents the same cause of action that was adjudicated in connection the previous suit. *SimpleAir*, 884 F.3d at 1165-69. "[T]he accused activity between [the previous and subsequent suits] must be 'essentially the same' for claim preclusion to apply." *Id*. at 1167 (quoting *Acumed LLC v. Stryker Corp.*, 525 F.3d 1319, 1324 (Fed. Cir. 2008)).

1. The Accused Product Is the Same

In an ANDA case, "the 'product' is the drug described in the ANDA." *Senju*, 746 F.3d at 1349-50. In the First and Second Wave Suits, Azurity alleged infringement and requested a declaratory judgment of infringement based on Bionpharma's ANDA and the 1 mg/mL enalapril maleate oral solution described therein. Shrestha Decl. Ex. A, D. Del. 18-1962 ECF No. 1, Compl. ¶¶ 23-37; *id*. at Ex. B, D. Del. 19-1067 ECF No. 1, Compl. ¶¶ 15-19; *id*. at Ex. J, Second Wave Suit, ECF No. 49, Second Am. Compl. ¶¶ 29-49. In the instant Third Wave Suit, Azurity alleges infringement and requests a declaratory judgment of infringement based on the same "accused product"—Bionpharma's ANDA and the 1 mg/mL enalapril maleate oral solution described therein. ECF No. 1, Compl. ¶¶ 22-40. "Because the product in the [instant Third

Wave Suit] completely overlaps with the product in the [First and Second Wave Suits], there is on that basis no new cause of action." *Senju*, 746 F.3d at 1350.

2. The '023 Patent Is Essentially the Same as the First and Second Wave Patents

The next part of the claim preclusion inquiry focuses on whether essentially "the same patent rights" that were involved in the earlier actions are involved in the instant action. *Id.*; *SimpleAir*, 884 F.3d at 1167. In *SimpleAir*, the Federal Circuit set forth the standard for evaluating whether essentially the same patent rights are involved when different patents are asserted in the earlier and later-filed actions:

> As the accused activity between two cases must be "essentially the same" for claim preclusion to apply, *see Acumed*, 525 F.3d at 1324, we adopt that standard for comparison of the claims between asserted patents as well. Thus, where different patents are asserted in a first and second suit, a judgment in the first suit will trigger claim preclusion only if the scope of the asserted patent claims in the two suits is essentially the same. In applying that standard to the particular context here, we conclude that claims which are patentably indistinct are essentially the same.

SimpleAir, 884 F.3d at 1167. "A later patent claim 'is not patentably distinct from an earlier claim if the later claim is obvious over, or anticipated by, the earlier claim.'" *Hubbell*, 709 F.3d at 1145 (quoting *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001)).

a. Azurity's Terminal Disclaimer Is Evidence that the '023 Patent Claims Are Patentably Indistinct

As explained above, during prosecution of the '587 application (which issued into the '023 patent), the claims that ultimately issued were all rejected on obviousness-type double patenting grounds over several of the First and Second Wave Patents. With respect to that rejection, the PTO Examiner stated the following:

> Claims of the '008, '745, '868, '482, '476, and ,621 [sic] are generally drawn towards stable oral liquid formulations comprising enalapril, a buffer comprising citric acid and sodium citrate dehydrate [sic]; a preservative, sweetener and water; wherein the pH of the formulation is less than about 3.5 or about 4.0; wherein the formulation is stable at about 5±3 °C for at least 18 months-24 months. Claims of the '008, '745, '868, '482, '476, and

> ,621 [sic], all specify the inclusion of the buffer in their system, which is implied in the instant claims in claims which recite the pH requirement of the composition. Thus, ***claims of '008, '745, '868, '482, '476, and ,621 [sic] of [sic] drawn to a species of the instantly claimed formulation. The ordinarily skilled artisan would find it prima facie obvious to arrive at the instantly claimed invention in view of the compositions described in the claims of '008, '745, '868, '482, '476, and ,621 [sic][.]***
>
> Accordingly, ***the instantly claimed invention is an obvious variant of the invention claimed in '008, '745, '868, '482, '476, and ,621 [sic][.]***

Shrestha Decl. Ex. V, '587 PH, Apr. 19, 2021 Office Action at 11 (BION-ESOL-00038455) (emphasis added). As also explained above, rather than contest and traverse the PTO's obviousness-type double-patenting rejection, Azurity filed a terminal disclaimer tying the term of the '023 patent to the terms of the First and Second Wave Patents that formed the basis of the rejection.

While the Federal Circuit in *SimpleAir* made clear that submission of a terminal disclaimer to obviate an obviousness-type double patenting rejection during prosecution is not tantamount to an admission by the applicant that the claims being examined are patentably indistinct from an earlier parent application or patent, the court also emphasized that the disclaimer "is a strong clue that a patent examiner and, by concession, the applicant, thought the claims in the continuation [patent] lacked a patentable distinction over the parent [patent]." *SimpleAir*, 884 F.3d at 1168. This "strong clue" must be followed up with a comparison of the claims of the continuation patent with the claims of the parent patent to confirm a lack of patentable distinction. *Id*. As explained below, just a cursory comparison of the claims of the '023 patent with claims of the First and Second Wave Patents confirms no patentable distinction and that, therefore, the claims of the '023 patent are "essentially the same" as the claims Bionpharma defeated in the First and Second Wave Suits.

b. The '023 Patent Claims Are Anticipated or Rendered Obvious by the First and Second Wave Patent Claims

The PTO had it absolutely correct during prosecution of the '587 application when it observed that the "claims of [the First and Second Wave Patents are] drawn to a species of the instantly claimed formulation." Shrestha Decl. Ex. V, '587 PH, Apr. 19, 2021 Office Action at 11 (BION-ESOL-00038455). Federal Circuit "case law firmly establishes that a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim." *Eli Lilly*, 251 F.3d at 971. As plainly evident from the discussion below, nearly all of the claims of the '023 patent are anticipated by claims of the First and Second Wave Patents. Thus, the '023 patent claims are patentably indistinct from the claims of the First and Second Wave Patents, and Azurity is barred from asserting '023 patent against Bionpharma.

i. Claim 1 of the '023 Patent Is Anticipated

For example, as demonstrated in the table below, claim 1 of the '023 patent (the sole independent claim), is anticipated[10] by claim 1 of the '868 patent:

Claim 1 of the '023 Patent	**Claim 1 of the '868 Patent (with elements rearranged to match relevant limitations of '023 patent claim 1)**
Claim 1. A stable oral liquid formulation, consisting essentially of:	Claim 1. A stable oral liquid formulation, consisting essentially of:
(i) about 0.6 to about 1.2 mg/ml enalapril or a pharmaceutically acceptable salt or solvate thereof;	(i) about 0.6 to about 1.2 mg/ml enalapril or a pharmaceutically acceptable salt or solvate thereof;
(ii) a sweetener	wherein the formulation optionally comprises a sweetener, a flavoring agent, or both;
	(ii) a buffer to maintain the pH about 4.5 or below, wherein the buffer concentration is

[10] A patent claim is anticipated "if a single prior art reference discloses each and every limitation of the claimed invention." *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 958 (Fed. Cir. 2014).

	about 5 mM to about 20 mM;
(iii) a preservative, wherein the preservative comprises sodium benzoate, a paraben or a mixture of parabens;	(iii) about 1 mg/ml of a preservative that is sodium benzoate; and
(iv) water, and	(iv) water,
(v) optionally a flavoring agent;	wherein the formulation optionally comprises a sweetener, a flavoring agent, or both;
wherein the formulation is stable at about 5±3° C. for at least 12 months; and	wherein the formulation is stable at about 5±3° C. for at least 12 months; and
wherein the stable oral liquid formulation has about 95% w/w or greater of the initial enalapril amount and about 5% w/w or less total impurity or related substances at the end of the given storage period.	wherein the stable oral liquid formulation has about 95% w/w or greater of the initial enalapril amount and about 5% w/w or less total impurity or related substances at the end of the given storage period.

ECF No. 1-1, Compl. Ex. A, ’023 patent at claim 1; Shrestha Decl. Ex. K, ’868 patent at claim 1. As can be seen, all of the required limitations of claim 1 of the ’023 patent are expressly found in claim 1 of the ’868 patent, one of the Second Wave Patents. Claim 1 of the ’868 patent essentially claims a subgenus of the enalapril liquids claimed in ’023 patent claim 1. Similarly, claim 2 of the ’745 patent, one of the First Wave Patents, anticipates claim 1 of the ’023 patent (with sucralose, recited in claim 2 of the ’745 patent, satisfying the “sweetener” limitation of claim 1 of the ’023 patent (claim 6 of the ’023 patent identifies sucralose as a sweetener)). *Compare* ECF No. 1-1, Compl. Ex. A, ’023 patent at claim 1, *with* Shrestha Decl. Ex. E, ’745 patent at claim 2.

Regarding the buffer elements of claim 1 of the ’868 patent and claim 2 of the ’745 patent, while claim 1 of the ’023 patent does not expressly recite a buffer element, the claim nonetheless uses the transitional phraseology “consisting essentially of,” which signals “that the invention necessarily includes the listed ingredients [but] is open to unlisted ingredients that do

not materially affect the basic and novel properties of the invention." *HZNP Medicines LLC v. Actavis Labs. UT, Inc.*, 940 F.3d 680, 692–93 (Fed. Cir. 2019). Thus, the claims of the '023 patent can include components that do not materially affect "the basic and novel properties of the invention," and a buffer would most certainly qualify as such as component. *Id.* As the Delaware court found, a buffer maintains the pH of the enalapril liquid formulation which protects the enalapril and contributes to its stability. *Silvergate*, 2021 WL 1751148, at *19. Indeed, Azurity argued to the FDA that buffers such as citric acid/sodium citrate buffer used in Epaned® were critical to the stability of enalapril both during shelf life of the liquid formulation and after ingestion. *Id.* at *21. And during prosecution of the '587 application, Azurity pointed to the Example E formulations as written description support for the claims of the '023 patent (Shrestha Decl. Ex. V, '587 PH, Apr. 23, 2021 Response at 6 (BION-ESOL-00038474))—all of those formulations use citric acid/sodium citrate buffer systems. *Silvergate*, 2021 WL 1751148, at *14. Finally, as explained above, Azurity has listed the '023 patent in the FDA's Orange Book for Epaned®, which means that Azurity believes that the claims of the '023 patent cover Epaned®, which contains a citric acid/sodium citrate buffer. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(b). Thus, the claims of the '023 patent may include a separate buffer component.[11]

Because claim 1 of the '023 patent is anticipated by at least claim 1 of the '868 patent and claim 2 of the '745 patent, claim 1 of the '023 patent is patentably indistinct from the claims of the First and Second Wave Patents, and assertion of claim 1 of the '023 patent against Bionpharma is barred.

[11] Indeed, the Delaware court found that the only data demonstrating stability for 12 months or longer at refrigerated conditions (5±3° C) in the common specification were for the Example E formulations, which all contain citric acid/sodium citrate buffer systems. *Silvergate*, 2021 WL 1751148, at *14.

ii. The "Extended Stability Claims" (Claims 2-3) Are Anticipated

Claim 2 of the '023 patent depends from claim 1 and requires that the enalapril liquid formulation be stable "at about 5±3° C. for at least 18 months," while claim 3 of the '023 patent requires the formulation to be stable "at about 5±3° C. for at least 24 months." ECF No. 1-1, Compl. Ex. A, '023 patent at claims. Claims 11 and 12 of the '868 patent, which depend from claim 1 and contain all of its limitations, expressly disclose these additional limitations (Shrestha Decl. Ex. K, '868 patent at claims), and therefore claims 11 and 12 of the '868 patent anticipate claims 2 and 3 of the '023 patent. Thus, claims 2 and 3 of the '023 patent are patentably indistinct from the claims of the First and Second Wave Patents, and Azurity is barred from asserting them against Bionpharma.

iii. The "pH Range Claims" (Claims 4-5) Are Anticipated

Claim 4 of the '023 patent depends from claim 1 and requires that the formulation "maintains a pH between about 3 and about 4 for at least 3 months at about 5±3° C.," while claim 5, which also depends from claim 1, requires pH be maintained at the same range for at least 12 months (and at the same temperature). ECF No. 1-1, Compl. Ex. A, '023 patent at claims. Claim 9 of the '868 patent, which depends from claim 1, recites that the pH is maintained "between about 3 and about 4," and claim 1 of the '868 patent requires stability for at least 12 months. Shrestha Decl. Ex. K, '868 patent at claims. As the Delaware court found, maintaining pH contributes to stability for the shelf-life of the formulation. *Silvergate*, 2021 WL 1751148, at *19. As such, claim 9 of the '868 patent anticipates both claims 4 and 5 of the '023 patent. Thus, claims 4 and 5 of the '023 patent are patentably indistinct from the claims of the First and Second Wave Patents, and Azurity is barred from asserting them against Bionpharma.

iv. The "Sucralose Claims" (Claims 6-7) Are Anticipated

Claim 6 of the '023 patent depends from claim 1 and specifies that the sweetener is sucralose, while claim 7 depends from claim 6 and specifies that the sucralose is present "in about 0.5 mg/ml to about 0.9 mg/ml in the oral liquid formulation." ECF No. 1-1, Compl. Ex. A, '023 patent at claims. Both claims are anticipated by claim 2 of the '745 patent, which depends from claim 1 and specifies the addition of "about 0.5 to about 0.8 mg/ml sucralose." Shrestha Decl. Ex. E, '745 patent at claims. Thus, claims 6 and 7 of the '023 patent are patentably indistinct from the claims of the First and Second Wave Patents, and Azurity is barred from asserting them against Bionpharma.

v. The "Saccharin Claims" (Claims 8-9) Are Obvious

It is common knowledge that saccharin is a sweetener used to sweeten products such as beverages, candies, and medicinal products. There can be no real dispute that a POSA would readily understand that saccharin and its salts—required as the sweetener by claim 8 of the '023 patent and at a specific concentration in claim 9 of the '023 patent (ECF No. 1-1, Compl. Ex. A, '023 patent at claims)—are sweeteners suitable for use in the formulations claimed in the First and Second Wave Patents, even though the claims of those patents do not expressly mention saccharin or its salts. Indeed, the common specification expressly identifies saccharin and its salts as suitable sweeteners for use in the claimed liquids. Shrestha Decl. Ex. K, '868 patent at 8:35-53. Thus, claims 8 and 9 are obvious in view of, for example, '868 patent claim 1 and '745 patent claim 2. As such, they are patentably indistinct from the claims of the First and Second Wave Patents, and Azurity is barred from asserting them against Bionpharma.

vi. Claims 10-12, 17-18, and 20 Are Anticipated

Claim 20 of the '023 patent depends from claim 1 and essentially narrows each of the elements recited in claim 1. As demonstrated below, claim 20 is anticipated by at least claim 18 of the '008 patent (one of the First Wave Patents):

Claim 20 of the '023 Patent (written to incorporate claim 1 elements)	**Claim 18 of the '008 Patent (with elements rearranged to correspond to relevant limitations of '023 patent claim 20)**
Claim 20. The stable oral liquid formulation of claim 1, consisting essentially of:	Claim 18. A stable oral liquid formulation, consisting essentially of:
(i) about 1.0 mg/ml enalapril or a pharmaceutically acceptable salt or solvate thereof;	(i) about 1 mg/ml enalapril maleate;
(ii) a sweetener that is sucralose or sodium saccharin;	(ii) about 0.70 mg/ml of a sweetener that is sucralose;
	(iii) a buffer comprising about 1.82 mg/ml citric acid and about 0.15 mg/ml sodium citrate dihydrate;
(iii) a preservative, wherein the preservative comprises sodium benzoate that is present at about 0.2 mg/ml to about 1.2 mg/ml in the oral liquid formulation;	(iv) about 1 mg/ml of a preservative that is sodium benzoate;
(iv) water, and	(vi) water,
(v) optionally a flavoring agent;	(v) a flavoring agent;
	wherein the pH of the formulation is less than about 3.5 adjusted by sodium hydroxide or hydrochloric acid if needed; and
wherein the formulation is stable at about 5±3° C. for at least 12 months; and	wherein the formulation is stable at about 5±3° C. for at least 12 months;
wherein the stable oral liquid formulation has about 95% w/w or greater of the initial enalapril amount and about 5% w/w or less total impurity or related substances at the end	wherein the stable oral liquid formulation has about 95% or greater of the initial enalapril amount and about 5% w/w or less total impurities or related substances at the end of

of the given storage period.	the given storage period.

ECF No. 1-1, Compl. Ex. A, '023 patent at claim 1; Shrestha Decl. Ex. C, '008 patent at claim 18. As shown above, claim 18 of the '008 patent falls entirely within the scope of, and thus anticipates, claim 20 of the '023 patent. As apparent from the above table, claim 18 of the '008 patent also anticipates claims 10 (requires a flavoring agent), 12 (requires 1.0 mg/ml enalapril or salt/solvate), 17 (requires sodium benzoate), and 18 (requires "about 0.2 mg/ml to about 1.2 mg/ml" sodium benzoate) of the '023 patent.

Claim 11 recites "the stable oral liquid formulation of claim 1, wherein the enalapril or a pharmaceutically acceptable salt or solvate therefore functions as a buffer." ECF No. 1-1, Compl. Ex. A, '023 patent at claim 11. One of the named inventors, Gerold Mosher, who submitted a declaration during prosecution of the '587 application, argued to the PTO that enalapril maleate has inherent buffer properties. Shrestha Decl. Ex __, '587 PH, Mosher Decl. at 5 (BION-ESOL-00038484) ("Formulations of Table 1 do not require additional buffering agents other than enalapril maleate, which is a salt of an amino acid. As an amino acid, an enalapril molecule contains carboxylic acid and amine groups that can dissociate and thus balance the pH variations."). Thus, according to one of the named inventors, claim 11 of the '023 patent recites an inherent property of enalapril. "A single prior art reference may anticipate without disclosing a feature of the claimed invention if such feature is necessarily present, or inherent, in that reference." *Allergan*, 754 F.3d at 958. Because, according to Dr. Mosher and Azurity, the enalapril maleate of claim 18 of the '008 patent would inherently act as a buffer, claim 18 of the '008 patent anticipates claim 11 of the '023 patent.

As such, claims 10-12, 17-18, and 20 of the '023 patent are patentably indistinct from the claims of the First and Second Wave Patents, and Azurity is barred from asserting them against Bionpharma.

vii. The "Paraben Claims" (Claims 13-16 and 19) Are Anticipated or Obvious

Claims 13-16 of the '023 patent, each of which depends from claim 1 and specifies that the preservative is a paraben (or paraben mixture), are anticipated by claims of the First and Second Wave Patents. For example, as demonstrated below, claim 16 of the '023 patent is anticipated by claim 27 of the '621 patent (which depends from claim 19):

Claim 16 of the '023 Patent (written to incorporate claim 1 elements)	**Claim 27 of the '621 Patent (written to incorporate claim 19 elements, and with elements rearranged to match claim 16 of the '023 patent)**
Claim 16. A stable oral liquid formulation, consisting essentially of:	Claim 27. A stable oral liquid formulation, consisting essentially of:
(i) about 0.6 to about 1.2 mg/ml enalapril or a pharmaceutically acceptable salt or solvate thereof;	(i) about 0.6 to about 1.2 mg/ml enalapril or a pharmaceutically acceptable salt or solvate thereof;
(ii) a sweetener;	wherein the formulation optionally comprises a sweetener, a flavoring agent, or both;
	(ii) a buffer to maintain the pH about 4.5 or below, wherein the buffer concentration is about 5 mM to about 20 mM;
(iii) a preservative, wherein the preservative comprises a paraben or a mixture of parabens present at about 0.1 mg/ml to about 2 mg/ml;	(iii) a preservative, wherein the preservative is methylparaben, ethylparaben, propylparaben, butylparaben, or a combination thereof present at about 0.1 mg/ml to about 2 mg/ml;
(iv) water, and	(iv) water,
(v) optionally a flavoring agent;	wherein the formulation optionally comprises a sweetener, a flavoring agent, or both;

	wherein the pH of the formulation is less than about 3.5 adjusted by sodium hydroxide or hydrochloric acid if needed; and
wherein the formulation is stable at about 5±3° C. for at least 12 months; and	wherein the formulation is stable at about 5±3° C. for at least 12 months; and
wherein the stable oral liquid formulation has about 95% w/w or greater of the initial enalapril amount and about 5% w/w or less total impurity or related substances at the end of the given storage period.	wherein the stable oral liquid formulation has about 95% w/w or greater of the initial enalapril amount and about 5% w/w or less total impurities or related substances at the end of the given storage period.

ECF No. 1-1, Compl. Ex. A, '023 patent at claim 1; Shrestha Decl. Ex. M, '621 patent at claim 27. As can be seen, claim 27 of the '621 patent is essentially a slightly narrower version of claim 16 of the '023 patent; stated differently, claim 27 of the '621 patent is essentially directed to a subgenus/species of claim 16 of the '023 patent. Because of this, and because claim 27 of the '621 patent discloses all of the elements of claim 16 of the '023 patent, claim 27 of the '621 patent anticipates claim 16 of the '023 patent. *Eli Lilly*, 251 F.3d at 971; *Allergan*, 754 F.3d at 958. For the same reasons, claims 13 (requires a mixture of parabens), 14 (paraben is methylparaben, ethylparaben, propylparaben, butylparaben, salts thereof, or combination thereof), and 15 (paraben mixture is methylparaben and propylparaben) of the '023 patent are also each anticipated by claim 27 of the '621 patent.

Finally, claim 19 of the '023 patent is essentially a combination of claims 24 and 27 of the '621 patent—like claim 27, claim 24 of the '621 patent depends from claim 19, but it specifies that the enalapril or pharmaceutically acceptable salt/solvate is present at 1.0 mg/ml. Thus, claim 24 of the '621 discloses the enalapril concentration of claim 19 of the '023 patent (1.0 mg/ml). The only difference between claim 19 of the '023 patent and claims 24 and 27 of the '621 patent is that claim 19 of the '023 patent specifies that the sweetener is sucralose or sodium saccharin; as explained above, claim 2 of the '745 patent provides this limitation, as it

discloses sucralose as a suitable sugar. Thus, claim 19 of the '023 patent is, at the very least, obvious over claims 24 and 27 of the '621 patent and claim 2 of the '745 patent.

As such, claims 13-16 and 19 of the '023 patent are patentably indistinct from the claims of the First and Second Wave Patents, and Azurity is barred from asserting them against Bionpharma.

CONCLUSION

As demonstrated above, the instant Third Wave Suit involves the same cause of action Azurity pursued against Bionpharma in connection with the First and Second Wave Suits, where Bionpharma prevailed on non-infringement. Azurity here seeks a second bite at the apple, in front of a different court, but its late-issuing '023 patent—with claims that are patentably indistinct from those of the First and Second Wave Patents—provides Azurity with no new cause of action. As the Federal Circuit has explained:

> Claim preclusion implicates both the weighty policies of judicial economy and fairness to parties. . . . It encourages reliance on judicial decisions, bars vexatious litigation, and frees the courts to resolve other disputes.

SimpleAir, 884 F.3d at 1169 (internal quotations and citations omitted). Chief Judge Stark's final judgment and dismissal order in the First and Second Wave Suits should be respected, and Bionpharma should not be subjected to the expense and trouble of the instant duplicative Third Wave Suit. Bionpharma respectfully requests dismissal of the Complaint (ECF No. 1) for failure to state a claim.

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